K030460

Attachment 4

MAR 0 7 2003

510(k) Summary

Submitter's Name, Address, and Date of Submission

Kenneth B. Herland
Vice President Regulatory Affairs
Brennen Medical, Inc.
1290 Hammond Road
St. Paul, MN. 55110

Phone: 651-429-7413
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Submitted: February 10, 2003

Device Name

Trade Name:	(trade name)
Classification Name:	Surgical Mesh, 21 CFR 878.3300
Common/Usual Name:	Surgical Mesh

Predicate Device

Brennen Biosynthetic Surgical Mesh Matrix (K982403) and Advanced UroScience Surgical Mesh (K993459).

Indication for Use

For use in the treatment of hernias where the connective tissue has ruptured or as a sling material to support the repositioning and support of the bladder neck for female urinary incontinence resulting from urethral hypermobility or sphincter deficiency.

Device Description

(Trade name) is a sterile, processed and treated porcine skin, which is intended for use in the reconstruction of soft tissue deficiencies.

Technological Characteristics and Performance

The technological characteristics are the same or equivalent to the predicate device. Testing and review of the literature has demonstrated that the device is safe and effective and that its performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 7 2003

Brennen Medical, Inc.
Kenneth B. Herland
Vice President Regulatory Affairs
1290 Hammond Road
St. Paul, Minnesota 55110

Re: K030460
Trade/Device Name: Brennen Medical Biosynthetic Surgical Mesh Matrix
Regulation Number: 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: February 10, 2003
Received: February 12, 2003

Dear Mr. Herland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known) K030460

Device Name **Brennen Medical Biosynthetic Surgical Mesh Matrix**

Indications for Use

For use in the treatment of hernias where the connective tissue has ruptured or as a sling material to support the repositioning and support of the bladder neck for female urinary incontinence resulting from urethral hypermobility or sphincter deficiency.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030460

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use ____
(Per 21 CFR 801.109)

(Optimal Format 1-2-96)